MAY 1 9 2000

CooperVision

711 North Road
Scottsville, New York 14546
(716) 385-6810
Fax (716) 889-5688

510(k) Summary K001089

SUBMITTER:

Submitted on Behalf of:

Company Name:	Aspect Vision Care, Ltd.
Address:	Unit 2, South Point Hamble SO3 4RF Southampton UK
Phone:	011 44 1703 605200
Fax:	011 44 1703 605299

CONTACT PERSON:

Company Name:	Bonnie Tsymbal CooperVision, Inc.
Address:	711 North Road Scottsville, NY 14546
Phone:	(716) 264-3210
Fax:	(716) 889-5688

DATE SUMMARY PREPARED: March 31, 2000

TRADE NAME: Natural Touch (polymacon) Soft (hydrophilic) Contact Lens

COMMON NAME: Contact Lens

SUBSTANTIALLY EQUIVALENT TO:

The Natural Touch (polymacon) Soft (hydrophilic) Contact Lens for daily wear manufactured by Aspect Vision Care, Ltd. is equivalent to the Natural Touch (polymacon) Soft (hydrophilic) Contact Lens for daily wear (P820059) currently manufactured by Wesley-Jessen Corp. and CL Tinters Prosthetic (polymacon) Soft (hydrophilic) Contact Lens for daily wear K984259). Both lenses are currently being marketed in the United States by CooperVision, Inc.

The Aspect Vision Care, Ltd. Natural Touch (polymacon) Soft (hydrophilic) Contact Lens for daily wear is substantially equivalent to the indications for use of Wesley-Jessen's Natural Touch (polymacon) Soft (hydrophilic) Contact Lens. Additionally the subject contact lens is equivalent and has similar and equivalent characteristics and properties as the Natural Touch (polymacon) contact lens approved under P820059 and the Prosthetic (polymacon) contact lens cleared under K984259.

The lens is in Lens Group 1, low water nonionic polymer as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the Natural Touch (polymacon) lens manufactured by Aspect Vision Care, Ltd. are equivalent to those of the Natural Touch manufactured by Wesley-Jessen and the Prosthetic (polymacon) lens manufactured by CL Tinters.

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DESCRIPTION of the DEVICE:

In the hydrated state, Natural Touch (polymacon) Soft (hydrophilic) Contact Lenses are soft and pliable. When placed on the human cornea, Natural Touch contact lenses act as a refracting medium to correctly focus light rays on the retina. The Natural Touch (polymacon) Soft (hydrophilic) Contact Lens contains a pigmented area that will superimpose and mask the color of the natural iris. Both the pupil and peripheral areas of the lens are left untinted.

The Natural Touch (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is available as a single vision lens. The lens material polymacon, is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) cross-linked with ethyleneglycol dimethacrylate (62%) and water (38%).

Natural Touch lenses are available in Sophisticated Blue (dark blue), Baby Blue (light blue), Hazel, Willow Green, Sultry Grey and Aqua Seas (turquoise). They are colored with a mixture of the following color additives in an iris pattern: chromium-cobalt aluminum oxide, titanium dioxide and iron oxides.

The Natural Touch (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera.

	Aspect Vision Natural Touch	**Wesley Jessen Natural Touch**	**CL-Tinters Prosthetic**
Material	polymacon	equivalent	equivalent
Material Classification	Hydrophilic Lens Group 1	equivalent	equivalent
Indication for Use	Daily Wear myopia and hyperopia	equivalent	equivalent
Water Content	38%	equivalent	equivalent
Light Transmittance	>97%	equivalent	equivalent
Dk (35°)	8.0×10^{-11}	equivalent	equivalent
Index of Refraction	1.44	1.43	1.44
Powers	+6.00 to −10.00	+4.00 to −10.00	+8.00 to −8.00
Pigments	chromium-cobalt aluminum oxide, titanium dioxide and iron oxides.	equivalent	equivalent
Tint Process	Three Stage Print Pad Printing, pre-lens forming	Two Stage Print Pad Printing, pre-lens forming	Three Stage Print Pad Printing, pre-lens forming
Manufacturing Method	molded	equivalent	equivalent

INDICATIONS FOR USE:

The Natural Touch (polymacon) Soft Hydrophilic Contact Lens is indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons that may exhibit

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astigmatism up to 2.00 Diopters that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.
The lenses are to be disinfected using either a thermal (heat) or chemical (not heat), including hydrogen peroxide.

This is the same indication as the Prosthetic (polymacon) Soft (hydrophilic) Contact Lens manufactured by CL-Tinters.

PRECLINICAL INFORMATION:

The results of toxicology testing, including Ocular Irritation, Cytotoxicity and Systemic Injection, have demonstrated that the subject lens is non-toxic. A leachability study was conducted to assess the color fastness of the listed dyes used to tint the Natural Touch (polymacon) Soft (hydrophilic) Contact Lens. The study demonstrates that after two weeks of extraction at 37° C in saline, undetectable levels (≤1 ppm) of dye were observed in the extraction solution.

The physical, optical and chemical properties of the subject Natural Touch (polymacon) Soft (hydrophilic) Contact Lens are equivalent to those of the Natural Touch (polymacon) Soft (hydrophilic) Contact Lens from Wesley Jessen and the Prosthetic (polymacon) Soft (hydrophilic) Contact Lens from CL Tinters since the lens provided to CL Tinters is the same as that provided for the subject Natural Touch.

CONCLUSIONS:

The information provided in this 510(k) establishes that the Natural Touch (polymacon) Soft (hydrophilic) Contact Lens manufactured by Aspect Vision is equivalent in optical, chemical and physical properties of the predicate device and does not raise any questions of safety or effectiveness. Therefore , the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2000

Ms. Bonnie Tsymbal
Manager, Regulatory Affairs
CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Re: K001089
Trade Name: Natural Touch (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: May 9, 2000
Received: May 11, 2000

Dear Ms. Tsymbal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indication for Use Statement

510(k) Number: K001089

Device Name: Natural Touch

Indication for Use:

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The lenses are to be disinfected using either a thermal (heat) or chemical (not heat), including hydrogen peroxide.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001089

Prescription Use ✓ OR Over-The-Counter ____
(Per 21 CFR 801.109)